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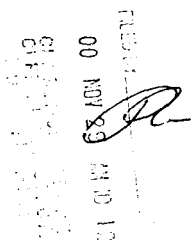
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 00-6329 CR-FERGUSON

18 U.S.C. §1341
21 U.S.C. § 331(q)(2)
21 U.S.C. § 333(a)(2)

MAGISTRATE JUDGE
SNOW



UNITED STATES OF AMERICA,

Plaintiff,

v.

HENRY BERNARD SCHUR, and
NICHOLAS LEVANDOSKI,

Defendants.

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS:

At all times relevant to this Information, unless otherwise stated:

1. Analyte Diagnostics, Inc., was a Florida corporation, which later became a wholly owned subsidiary of Simplex Medical Systems, Inc., also a Florida corporation, which later purchased a publically traded Colorado corporation, which conducted business under the name Simplex Medical Systems, Inc., which later became known as SMLX Technologies, Inc., a Colorado corporation, all hereinafter referred to as SMLX. SMLX's principal place of business was located in Broward County, Florida.

2. At various times relevant to this information, the defendant HENRY BERNARD SCHUR was an officer, director and president of SMLX.

3. At various times relevant to this information, the defendant NICHOLAS LEVANDOSKI was an officer, director and president of SMLX.

4. SMLX was engaged in the business of developing, manufacturing and marketing medical devices, to include a saliva based diagnostic test kit for detecting the presence of HIV antibodies in human saliva, which was marketed under the name "Simplex Rapid HIV Saliva Test."

5. The United States Food and Drug Administration ("FDA") was the agency of the United States government responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in the diagnosis or treatment of disease or other conditions in humans are safe and effective for their intended medical uses and that the labeling of such devices bore true and accurate information. The FDA carried out this responsibility by regulating and monitoring the manufacturing, processing, packaging, labeling and shipment of medical devices.

6. Under the Federal Food, Drug and Cosmetic Act (the Food and Drug Act), 21 U.S.C. § 321(h), a medical "device" was defined, in relevant part, as "an instrument, apparatus, implement, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or animals, . . . and which is not dependent upon being metabolized for achievement of its primary intended purposes."

7. Pursuant to 21 U.S.C. § 360c(f)(1) and 360e the saliva based HIV test kits relevant to this information are Class III medical devices.

8. Manufacturers of medical devices were required under the Food and Drug Act to obtain FDA "approval" or "clearance" prior to distributing the devices in interstate commerce. The Food and Drug Act defined "interstate commerce," in pertinent part, as meaning "commerce between any State or Territory and any place outside thereof . . ." 21 U.S.C. § 321(b).

9. The medical devices relevant to this information could only be lawfully introduced into interstate commerce if they were (1) approved by the FDA in the form of an approved application for premarket approval ("PMA") pursuant to 21 U.S.C. § 360(e); (2) found to be substantially equivalent to a device on the market prior to May 28, 1976, or to a subsequently approved Class I or II device, pursuant to 21 U.S.C. § 360(k); or (3) exempted from such approval requirements by an approved application for an investigational device exemption ("IDE"), pursuant to 21 U.S.C. § 360j(g).

10. The medical devices relevant to this information could be lawfully exported from the United States without the above described FDA "approvals" or "clearances" under one of two alternative conditions. First, a person may export an unapproved Class III device pursuant to 21 U.S.C. § 381(e)(2) if the device meets the criteria of 21 U.S.C. § 381(e)(1) and the FDA has determined that the device is not contrary to the public health and safety, and has the approval of the country to which it is intended for export. Second, a person may export an unapproved Class III device under 21 U.S.C. § 382 to any country if the device complies with the laws of that country and has a valid marketing authorization in certain industrialized "listed" countries.

11. In addition to the requirements described in paragraphs 9 and 10 of this information, all medical devices, whether for domestic shipment or export, were required to be manufactured in compliance with "current good manufacturing practices." 21 U.S.C. §§ 360(j) and 382(f)(1). Current

good manufacturing practices (cGMP) prescribe the requirements for manufacturing, testing, storing, packaging and distributing a medical device so that the device will be safe and effective. These requirements are set forth in regulations issued by the FDA.

COUNT 1

12. The allegations set forth in paragraphs 1 through 11 of the General Allegations section are realleged and incorporation herein by reference.

INTRODUCTION:

13. The defendants, HENRY BERNARD SCHUR and NICHOLAS LEVANDOSKI, were integrally involved in the development and marketing of the Simplex Rapid HIV Saliva Test kits.

14. At all times relevant to this information, SMLX had not yet obtained FDA "clearance" or "approval" to market the Simplex Rapid HIV Saliva Test kits in the United States, and SMLX had not yet met the requirements to lawfully export Simplex Rapid HIV Saliva Test kits to foreign countries.

15. In order to generate revenue and in order to develop a market for the Simplex Rapid HIV Saliva Test kits, SCHUR and LEVANDOSKI endeavored to locate persons and entities who would be willing to purchase distributorship agreements granting them exclusive sales territories for the sale of the Simplex Rapid HIV Saliva Test kits.

16. The distributorship agreements were sold for territories covering entire countries. In order to purchase an exclusive distributorship, persons and entities were required to make large non-refundable deposits against future orders of Simplex Rapid HIV Saliva Test kits.

PURPOSE OF THE SCHEME:

17. From in or about June 1995, the exact date being unknown to the United States Attorney,

and continuing to on or about September 21, 1999, the defendants, HENRY BERNARD SCHUR and NICHOLAS LEVANDOSKI, devised a scheme to defraud Salterven International, S.A., Universal Labs, Inc., SDK Pharmaceuticals, Giant Export and Manufacturing Company, and others known and unknown to the United States Attorney, of money and other property through false and fraudulent pretenses, representations and promises regarding the efficacy of the Simplex Rapid HIV Saliva Test kits and regarding the FDA "clearance" and "approval" status of the Simplex Rapid HIV Saliva Test kits.

THE SCHEME:

18. It was a part of the scheme that the defendants, SCHUR and LEVANDOSKI, in order to induce persons and entities into purchasing and maintaining distributorship agreements provided the distributors and potential distributors with false and fraudulent information regarding the efficacy of the Simplex Rapid HIV Saliva Test kits.

19. In particular, SCHUR and LEVANDOSKI provided distributors and potential distributors with a fabricated clinical study allegedly performed by "Dr. Nicholas Levandoski" at the University of Miami, Jackson Memorial Hospital (University of Miami Study), which purported to establish the efficacy of the saliva collector and saliva based HIV testing process which were later used in the Simplex Rapid HIV Saliva Test kits.

20. SCHUR and LEVANDOSKI also provided distributors and potential distributors with a report of a clinical study of a competing brand of HIV test kit (Nassau County Study) that had been altered to indicate that the study was performed on the "SIMPLEX Brand" HIV test kit.

21. SCHUR and LEVANDOSKI also provided distributors and potential distributors with a report of a clinical study of the Simplex Rapid HIV Saliva Test kits conducted at the Broward

County Health Department (Broward County Study) that had been altered to indicate that the study had been conducted on many more test subjects than had actually been studied.

22. It was further a part of the scheme that the defendants, SCHUR and LEVANDOSKI, in order to induce persons and entities into purchasing and maintaining distributorship agreements, falsely represented that NICHOLAS LEVANDOSKI, who was identified as SMLX's scientist, had earned a Ph.D., when in fact, LEVANDOSKI had only earned a bachelor's degree.

23. It was further a part of the scheme that the defendants, SCHUR and LEVANDOSKI, in order to induce persons and entities into purchasing and maintaining distributorship agreements provided the distributors with an erroneously issued FDA Certificate of Exportability for Simplex Rapid HIV Saliva Test kits after the certificate had been rescinded by the FDA.

24. If was further a part of the scheme that the defendants, SCHUR and LEVANDOSKI, instructed the distributors and potential distributors to use the Nassau County Study, the Broward County Study, and the rescinded Certificate of Exportability in submissions to foreign regulators and in marketing materials in order to attempt to obtain approval to import and in order to sell the Simplex Rapid HIV Saliva Test kits in other countries.

MAILING:

25. On or about January 8, 1998, at Broward County, in the Southern District of Florida, and elsewhere, the defendants,

HENRY BERNARD SCHUR, and
NICHOLAS LEVANDOSKI,

for the purpose of executing the above described scheme to defraud and for obtaining money and property by false and fraudulent pretenses, representations and promises did knowingly and willfully cause to be delivered by the United States Postal Service, according to the directions thereon, certain

mail matter, that is, copies of the Nassau County Study, the Broward County Study, and the rescinded Certificate of Exportability, to a potential purchaser in Mexico City, Mexico, in violation of Title 18, United States Code, Sections 1341 and 2.

COUNT 2

26. The allegations set forth in paragraphs 1 through 11 of the General Allegations section are realleged and incorporation herein by reference.

27. On or about May 12, 1998, at Broward County, in the Southern District of Florida, and elsewhere, the defendants,

HENRY BERNARD SCHUR, and
NICHOLAS LEVANDOSKI,

did knowingly and willfully, with the intent to defraud and mislead the FDA, submit an Investigational Device Exemption Application to the FDA that was false and misleading in a material respect, in that the defendants knowingly included in the application falsified, exaggerated and altered test data relevant to the medical device for which they were seeking an Investigation Device Exemption, and which included false representations regarding the level of education defendant NICHOLAS LEVANDOSKI, the submitting authority, had obtained, in violation of Title 21, United States Code, Sections 331(q)(2) and 333(a)(2), and Title 18, United States Code, Section 2.

GUY A. LEWIS
UNITED STATES ATTORNEY

ROBERT N. NICHOLSON
ASSISTANT UNITED STATES ATTORNEY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

v.

HENRY SCHUR, et al

Court Division: (Select One)

___ Miami ___ Key West
X FTL ___ WPB ___ FTP

CASE NO. _____

CERTIFICATE OF TRIAL ATTORNEY*

Superseding Case Information:

New Defendant(s) Yes ___ No ___
Number of New Defendants ___
Total number of counts ___

I do hereby certify that:

1. I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.

2. I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. Section 3161.

3. Interpreter: (Yes or No) NO
List language and/or dialect _____

4. This case will take 1 days for the parties to try.

5. Please check appropriate category and type of offense listed below:

(Check only one)			(Check only one)	
I	0 to 5 days	X	Petty	
II	6 to 10 days		Minor	
III	11 to 20 days		Misdem.	
IV	21 to 60 days		Felony	X
V	61 days and over			

6. Has this case been previously filed in this District Court? (Yes or No) No
If yes:
Judge: _____ Case No. _____
(Attach copy of dispositive order)

Has a complaint been filed in this matter? (Yes or No) No
If yes:
Magistrate Case No. _____
Related Miscellaneous numbers: 99-4797-Snow
Defendant(s) in federal custody as of _____
Defendant(s) in state custody as of _____
Rule 20 from the _____ District of _____

Is this a potential death penalty case? (Yes or No) No

7. Does this case originate from a matter pending in the U. S. Attorney's Office prior to April 1, 1999? ___ Yes X No If yes, was it pending in the Central Region? ___ Yes ___ No

8. Did this case originate in the Narcotics Section, Miami? ___ Yes X No

ROBERT N. NICHOLSON
ASSISTANT UNITED STATES ATTORNEY
Florida Bar No. 933996

*Penalty Sheet(s) attached

REV.6/27/00

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
PENALTY SHEET

Defendant's Name: Henry Schur No.: _____

Count # I:
Mail Fraud; in violation of Title 18, United States Code, Section 1341

*Max Penalty: 5 years' imprisonment and a fine of up to the greater of $250,000 or twice the amount of the fraud.

Count # 2:
False statements to the FDA, in violation of Title 21, United States Code, Section 331(q)(2)

*Max Penalty: 3 years' imprisonment and a fine of up to $250,000

Count # :

*Max Penalty:

Count # :

*Max Penalty:

Count #:

*Max Penalty:

Count #:

*Max Penalty:

***Refers only to possible term of incarceration, does not include possible fines, restitution, special assessments, parole terms or forfeitures that may be applicable.**

REV. 12/12/96

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
PENALTY SHEET

Defendant's Name: Nicholas Levandoski No.: _____

Count # I:
Mail Fraud; in violation of Title 18, United States Code, Section 1341

*Max Penalty: 5 years' imprisonment and a fine of up to the greater of $250,000 or twice the amount of the fraud.

Count # 2:
False statements to the FDA, in violation of Title 21, United States Code, Section 331(q)(2)

*Max Penalty: 3 years' imprisonment and a fine of up to $250,000

Count # :

*Max Penalty:

Count # :

*Max Penalty:

Count #:

*Max Penalty:

Count #:

*Max Penalty:

***Refers only to possible term of incarceration, does not include possible fines, restitution, special assessments, parole terms or forfeitures that may be applicable.**

REV. 12/12/96